

JUN 15 2012

510(k) Summary

- 1. Company:**

Medyssey Co. Ltd.
722-3, 4F, Science Tower 4F
Dongducheon City
Gyeonggido, Korea
Tel: 82-31-879-0414
FAX: 82-31-879-0415
- 2. Contact:**

Michael Kvitnitsky
Chief Operating Officer
Medyssey Co. Ltd.
8001 N. Lincoln Ave.
Suite 401
Skokie, IL 60077
Tel: 847-982-0100
FAX: 888-518-9070
- 3. Proprietary Name:** Medyssey LT Cage System
- 4. Classification Name:** Intervertebral Body Fusion Device (21 CFR888.3080); Class II, Product Code MAX
- 5. Product Description:**

The Medyssey LT Cage System consists of cages of various widths and heights, which can be inserted between two lumbar or lumbrosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft. The Medyssey LT Cage System is to be used with supplemental fixation.

The device is offered in 64 sizes, with heights ranging from 8 – 15mm, lengths from 25 – 32mm and a width of 11mm. They are also available with 0°, 4° and 8° lordosis. The devices are manufactured from titanium alloy (Ti-6Al-4V) meeting ASTM F136 and are supplied non-sterile.

The purpose of this submission is to provide a device that is manufactured from titanium alloy, which is similar to the PEEK device currently available from Medyssey Co. Ltd.
- 6. Indications for Use:**

The LT Cage System is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

7. Summary of Technological Characteristics

The purpose of this special 510(k) is to provide a cage with the same dimension design and implant technique as the Medyssey LP Cage, but manufactured from titanium alloy meeting ASTM F136. The design and fundamental scientific technology of the subject Medyssey LT Cage are identical to the predicate device. The only difference is the material.

8. Identification of Legally Marketed Predicate Device

Documentation was provided, which demonstrates that the subject Medyssey LT Cage is substantially equivalent to the predicate Medyssey LP Cage cleared on April 8, 2011 under K110067. The only difference is the material of manufacture and several lumbar cage devices are manufactured from titanium alloy including the Medtronic PERIMETER Interbody Fusion Device (K111525, Aug. 25, 2011) and the Ray Cage (P950019).

9. Brief Discussion of Non-Clinical Tests Submitted

The subject and predicate Medyssey Cage devices are identical in indications for use, intended use, performance specifications, and fundamental technological characteristics. Assessment of the design change (alternate material) was completed in accordance with Medyssey design control procedures. The titanium material is stronger than the currently available PEEK material. In addition titanium is used in both spinal and general orthopedic implants and has no biocompatibility issues. No additional testing is required to support this submission. The predicate LP Cage was subjected to the following:

- Static Compression – ASTM F2077-03
- Static Torsion – ASTM F2077-03
- Static Compressive Shear – F207703
- Dynamic Compression – F2077-03
- Subsidence – ASTM F2267-04

10. Conclusions from Non-Clinical Tests

A risk analysis was completed. Based on the risk analysis and additional supporting documentation provided in this premarket notification submission, Medyssey believes that the subject Medyssey LT Cage is substantially equivalent to the Medyssey LP Cage.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 15 2012

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Medysy Co., Ltd.
% Mr. Michael Kvitnitsky
Chief Operating Officer
8001 North Lincoln Avenue
Skokie, Illinois 60077

Re: K121246
Trade/Device Name: Medyssey LT Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: May 29, 2012
Received: May 30, 2012

Dear Mr. Kvitnitsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

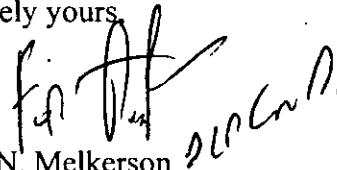
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K121246

Device Name: Medyssey LT Interbody Fusion Cage System

Indications for Use:

The LT Cage System is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

Prescription Use X

OR


Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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